

1 METHODS AND APPARATUS FOR TREATING THE WALL OF A BLOOD VESSEL WITH  
2 ELECTROMAGNETIC ENERGY

3

4 This application is a continuation-in-part of application  
5 serial number 10/358,523 filed 2/5/03 and application serial  
6 number 09/898,867, filed 7/3/01.

7

8 BACKGROUND OF THE INVENTION

9

10 1. Field of the Invention

11 The invention relates to the treatment and correction of  
12 blood vessels. More particularly the invention relates to methods  
13 and apparatus for automatically delivering treating energy to the  
14 interior of a blood vessel in an evenly distributed manner.

15

16 2. State of the Art

17 The human venous system of the lower limbs consists  
18 essentially of the superficial venous system and the deep venous  
19 system with perforating veins connecting the two systems. The  
20 superficial system includes the long or great saphenous vein and  
21 the short saphenous vein. The deep venous system includes the  
22 anterior and posterior tibial veins which unite to form the  
23 popliteal vein, which in turn becomes the femoral vein when joined  
24 by the short saphenous vein.

1        The venous systems contain numerous one-way valves for  
2 directing blood flow back to the heart. Venous valves are usually  
3 bicuspid valves, with each cusp forming a sack or reservoir for  
4 blood which, under pressure, forces the free surfaces of the cusps  
5 together to prevent retrograde flow of the blood and allow  
6 antegrade flow to the heart. An incompetent valve is a valve  
7 which is unable to close because the cusps do not form a proper  
8 seal and retrograde flow of blood cannot be stopped.

9

10      Incompetence in the venous system can result from vein  
11 dilation. Separation of the cusps of the venous valve at the  
12 commissure may occur as a result. Two venous diseases which often  
13 involve vein dilation are varicose veins and chronic venous  
14 insufficiency.

15

16      The varicose vein condition includes dilatation and  
17 tortuosity of the superficial veins of the lower limb, resulting  
18 in unsightly discoloration, pain and ulceration. Varicose veins  
19 often involve incompetence of one or more venous valves, which  
20 allow reflux of blood from the deep venous system to the  
21 superficial venous system or reflux within the superficial system.

22

23      Varicose veins are compatible with long life and rarely cause  
24 fatal complications, but the condition significantly decreases the

1 quality of life. Patients complain primarily of leg fatigue,  
2 dull, aching pains, ankle swelling, and ulcerations.  
3 Occasionally, thrombosis occurs in dilated subcutaneous channels,  
4 resulting in local pain, induration, edema, inflammation, and  
5 disability. In addition to those problems, the high visibility of  
6 the unattractive rope-like swellings and reddish skin blotches  
7 causes considerable distress for both men and women. Lastly,  
8 varicose eczema, which is a local reddened swollen and itching  
9 skin condition can occur and can spread to distant parts of the  
10 body (called an "Id reaction").

11

12 Phlebosclerosis, the destruction of venous channels by the  
13 injection of treating agents, has been used to treat varicose  
14 veins since 1853, when Cassaignae and Ebout used ferric chloride.  
15 Sodium salicylate, quinine, urea, and sodium chloride have also  
16 been used, but the agent more recently favored is sodium  
17 tetradecyl sulfate. In order for phlebosclerosis to be effective,  
18 it is necessary to evenly dispense the treating agent throughout  
19 the wall of the vein without using toxic levels of the treating  
20 agent. This is not particularly difficult for the smaller veins.  
21 However, it is quite difficult or nearly impossible in larger  
22 veins. When a larger vein is injected with a treating agent, the  
23 treating agent is quickly diluted by the substantially larger  
24 volume of blood which is not present in smaller veins. The result

1 is that the vein is sclerosed (injured) only in the vicinity of  
2 the injection. If the procedure is continued, and the injections  
3 are far apart, the vein often assumes a configuration resembling  
4 sausage links. The problem cannot be cured by injecting a more  
5 potent solution of treating agent, because the treating agent may  
6 become toxic at such a concentration.

7

8 Until recently, the preferred procedure for treating the  
9 great saphenous vein was surgical stripping. This highly invasive  
10 procedure involves making a 2.5 cm incision in the groin to expose  
11 the saphenofemoral junction, where the great saphenous vein and  
12 its branches are doubly ligated en masse with a heavy ligature.  
13 The distal portion of the vein is exposed through a 1 cm incision  
14 anterior to the medial malleolus, and a flat metal or plastic  
15 stripper is introduced to exit in the proximal saphenous vein.  
16 The leg is held vertically for 30 seconds to empty the venous tree  
17 before stripping the vein from the ankle to the groin. If the  
18 small saphenous vein is also incompetent, it is stripped at the  
19 same time from an incision posterior to the lateral malleolus to  
20 the popliteal space. After stripping the veins, the leg is held  
21 in the vertical position for three to four minutes to permit  
22 broken vessel ends to retract, constrict, and clot.

23

1        After the stripping procedure, collateral veins are removed  
2 by the avulsion-extraction technique. By working through small (5  
3 to 8 mm) transverse incisions, segments of vein 10 to 20 cm long  
4 can be removed by dissecting subcutaneously along the vein with a  
5 hemostat, and then grasping, avulsing, and removing the vein.  
6 With practice, long segments of vein in all quadrants can be  
7 removed through these small incisions. No attempt is made to  
8 ligate the branches or ends of the veins, since stripping has  
9 shown it to be unnecessary. Bleeding is controlled by elevation  
10 and pressure for two to four minutes. As many as 40 incisions are  
11 made in severe cases, but their small size and transverse  
12 direction permit closure with a single suture.

13

14       Before closure of the incisions, a rolled towel is rolled  
15 repeatedly from the knee to the ankle and from the knee to the  
16 groin to express any clots that may have accumulated. The groin  
17 incision is approximated with three 5-0 nylon mattress sutures and  
18 all other incisions are closed with a single suture.

19

20       As can be readily appreciated, the stripping and avulsion-  
21 extraction procedures are relatively invasive and require  
22 significant anaesthesia. It can therefore be appreciated that it  
23 would be desirable to provide an alternative, less invasive

1 procedure which would accomplish the same results as stripping and  
2 avulsion-extraction.

3

4 The two parent applications listed above describe methods and  
5 apparatus for delivering a fluid treating agent to the interior of  
6 a blood vessel.

7

8 Recently, a number of patents have issued disclosing the  
9 treatment of varicose veins with RF energy. Illustrative of these  
10 recent patents are: U.S. Patent #6,200,312 entitled "Expandable  
11 Vein Ligator Catheter Having Multiple Electrode Leads"; U.S.  
12 Patent #6,179,832 entitled "Expandable Catheter Having Two Sets of  
13 Electrodes"; U.S. Patent #6,165,172 entitled "Expandable Vein  
14 Ligator Catheter and Method of Use"; U.S. Patent #6,152,899  
15 entitled "Expandable Catheter Having Improved Electrode Design,  
16 and Method for Applying Energy"; U.S. Patent #6,071,277 entitled  
17 "Method and Apparatus for Reducing the Size of a Hollow Anatomical  
18 Structure"; U.S. Patent #6,036,687 entitled "Method and Apparatus  
19 for Treating Venous Insufficiency"; U.S. Patent #6,033,398  
20 entitled "Method and Apparatus for Treating Venous Insufficiency  
21 Using Directionally Applied Energy"; U.S. Patent #6,014,589  
22 entitled "Catheter Having Expandable Electrodes and Adjustable  
23 Stent"; U.S. Patent #5,810,847 entitled "Method and Apparatus for  
24 Minimally Invasive Treatment of Chronic Venous Insufficiency";

1 U.S. Patent #5,730,136 entitled "Venous Pump Efficiency Test  
2 System And Method"; and U.S. Patent #5,609,598 entitled "Method  
3 and Apparatus for Minimally Invasive Treatment of Chronic Venous  
4 Insufficiency". These patents generally disclose a catheter  
5 having an electrode tip which is switchably coupled to a source of  
6 RF energy. The catheter is positioned within the vein to be  
7 treated, and the electrodes on the catheter are moved toward one  
8 side of the vein. RF energy is applied to cause localized heating  
9 and corresponding shrinkage of the adjacent venous tissue. After  
10 treating one section of the vein, the catheter can be repositioned  
11 to place the electrodes to treat different sections of the vein.  
12 For even and consistent cauterization, RF treatment requires that  
13 the practitioner be keenly aware of the procedure time. If RF  
14 energy is applied for too long, it can cause undesired burns. If  
15 RF energy is not applied long enough, the treatment is  
16 ineffective.

17

18 In addition to RF treatment, laser treatment has been used  
19 with some success. See, e.g. U.S. Patents Numbers 6,200,332,  
20 entitled "Device and Method for Underskin Laser Treatments";  
21 6,197,020, entitled "Laser Apparatus for Subsurface Cutaneous  
22 Treatment"; and 6,096,029, entitled "Laser Method for Subsurface  
23 Cutaneous Treatment". Laser treatment shares the same  
24 disadvantage of RF treatment. In particular, as with the RF

1 devices, the practitioner must be very careful as to the intensity  
2 and duration of the treatment to assure that the treatment is  
3 effective but without causing undesired burns.

4

5 EM treatment is also used to treat other blood vessel  
6 conditions such as arterial blockages. It would also be  
7 advantageous to control the intensity and duration of treatment in  
8 these procedures.

9

10 INCORPORATION BY REFERENCE

11

12 The disclosures of all of the aforementioned U.S. Patents as  
13 well as the disclosures of the two parent applications are hereby  
14 incorporated by reference herein.

15

16 SUMMARY OF THE INVENTION

17

18 It is therefore an object of the invention to provide methods  
19 and apparatus for the minimally invasive treatment of blood  
20 vessels.

21

22 It is also an object of the invention to provide methods and  
23 apparatus for the minimally invasive treatment of blood vessels  
24 wherein the wall of the blood vessel is evenly treated.

1       Another object of the invention is to provide methods and  
2 apparatus for the minimally invasive treatment of blood vessels  
3 which do not utilize high concentration treating agents.

4

5       Yet another object of the invention is to provide methods and  
6 apparatus for the minimally invasive treatment of blood vessels  
7 which do not require that the practitioner carefully monitor the  
8 duration, rate, or progression of treatment.

9

10       In accord with these objects which will be discussed in  
11 detail below, the method of the invention is to automatically  
12 activate an RF, laser, or similar device (hereinafter  
13 "electromagnetic" or "EM" device) as it is moved through a blood  
14 vessel so that an even amount of energy is dispensed per linear  
15 unit of the blood vessel. Within reasonable limits, the EM device  
16 may be moved either slowly or quickly and still dispense the same  
17 amount of energy per linear unit of blood vessel length.

18

19       An apparatus according to the present invention includes an  
20 automatic switch for use with an EM device whereby activation of  
21 the EM device is automatically controlled as the EM device is  
22 moved through a blood vessel.

23

1 Several embodiments of a suitable apparatus for performing  
2 the method of the invention are disclosed using electromechanical,  
3 optical, and magnetic switching.

4

5 Additional objects and advantages of the invention will  
6 become apparent to those skilled in the art upon reference to the  
7 detailed description taken in conjunction with the provided  
8 figures.

9

10 BRIEF DESCRIPTION OF THE DRAWINGS

11

12 Figure 1 is a high level schematic view of an apparatus for  
13 carrying out the methods of the invention;

14

15 Figure 2 illustrates in part one embodiment of the apparatus  
16 of Figure 1;

17

18 Figure 3 illustrates in part a second embodiment of the  
19 apparatus of Figure 1;

20

21 Figure 4 illustrates in part a third embodiment of the  
22 apparatus of Figure 1;

23

1       Figure 5 illustrates in part a fourth embodiment of the  
2 apparatus of Figure 1;

3

4       Figure 6 illustrates in part a fifth embodiment of the  
5 apparatus of Figure 1;

6

7       Figure 7 illustrates in part a sixth embodiment of the  
8 apparatus of Figure 1;

9

10       Figure 8 is a high level schematic view of an actuator handle  
11 incorporating an apparatus for carrying out the methods of the  
12 invention;

13

14       Figure 9 is a high level schematic rear end view of the  
15 trigger engagement of the actuator of Figure 8;

16

17       Figure 10 is an enlarged view of a ratchet engagement of the  
18 actuator of Figures 8 and 9; and

19

20       Figure 11 is a high level schematic view of a seventh  
21 embodiment of the invention.

22

1           DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS  
2

3           Referring now to Figure 1, an apparatus 10 for performing the  
4        methods of the invention includes an EM device 12, a power supply  
5        14, and a rotary switch 16. The EM device 12 may be any of the  
6        prior art electrocautery or laser devices which operate on pulsed  
7        power. These devices are in the form of a catheter tube having a  
8        proximal end 12a and a distal end 12b. The proximal end 12a is  
9        electrically coupled to the power supply 14 and the distal end 12b  
10      has either a plurality of electrodes (not shown) or an optical  
11      element for emitting laser light. Whereas the prior art devices  
12      are coupled to a manually operated switch (not shown) the  
13      apparatus of the invention is coupled to an automatically operated  
14      switch 16.

15

16      According to this embodiment of an apparatus for performing  
17      the methods of the invention the automatically operated switch 16  
18      includes a pair of rollers 18, 20 which engage the EM device 12.  
19      One of the rollers, e.g. 20, is shown in detail in Figure 2. A  
20      side surface of roller 20 is divided into multiple sectors, e.g.  
21      20a-20h, some of the sectors are conductive (20b, 20d, 20f, and  
22      20h) and the other sectors are not conductive (20a, 20c, 20e, and  
23      20g). A pair of conductors 22, 24 which are coupled to the power

1 supply 14 are provided with wiper contacts 22a, 24a which are  
2 arranged to engage the side surface of the roller 20.

3

4 The method of operating the apparatus 10 includes deploying  
5 the EM device 12 within a blood vessel 2 in the conventional way.  
6 The switch 16 is coupled to the device 12, typically near the  
7 proximal end 12a. The device 12 is then withdrawn from the blood  
8 vessel 2 by pulling it in the direction shown by the arrow "A" in  
9 Figure 1. Those skilled in the art will appreciate that as the  
10 device 12 is pulled through the switch 16 in the direction of the  
11 arrow "A", the rollers 18 and 20 will rotate as indicated by the  
12 arrows "B" and "C". As the roller 20 rotates, the wiper contacts  
13 22a, 24a of the conductors 22, 24 will alternately contact  
14 conductive sectors and non-conductive sectors on the side surface  
15 of the roller 20. Each time the contacts pass over a conductive  
16 sector, the EM device will pulse once for a selected duration.  
17 The duration of the pulse is controlled by the power supply  
18 according to the prior art. The invention automatically dispenses  
19 a predetermined number of pulses per unit length of the blood  
20 vessel. It will be appreciated that the number of pulses per unit  
21 length of blood vessel (NPUL) can be computed using the equation  
22  $NPUL = ncs/\pi d$ , where ncs is the number of conductive sectors and d  
23 is the diameter of the roller.

24

1       Figure 3 shows a second embodiment of an automatic switch  
2 where one of the rollers 118 has a plurality of spaced apart holes  
3 or transparencies 118a-118i. A light source 126 is located on one  
4 side of the roller 118 and a light detector 128 is located at the  
5 other side. The detector 128 is coupled to a switching circuit  
6 130 which is coupled to the power supply of the EM device. It  
7 will be appreciated that as the roller 118 rotates, light from the  
8 source 126 is alternately blocked and un-blocked due to the  
9 spacing of the holes or transparencies. The switching circuit 130  
10 is designed to produce alternating open and closed connections  
11 depending on the presence or absence of light at the detector.  
12

13       Figure 4 shows a third embodiment of an automatic switch  
14 where one of the rollers 220 has a plurality of spaced apart bumps  
15 220a-220l. A roller 226 is mounted at one end of a lever 228, the  
16 other end having an electrically conductive member 230.  
17 Conductors 222, 224 are arranged alongside the conductor 230 and  
18 are coupled to the power supply of the EM device. The roller 226  
19 is biased against the roller 220 by a spring 232. It will be  
20 appreciated that the roller 220 functions as a cam and the roller  
21 226 functions as a cam follower. As the roller 220 rotates as  
22 shown by the arrow D, the lever 228 moves back and forth as  
23 indicated by the arrow E. This causes the electrically conductive  
24 member 230 to move back and forth as shown by the arrow F, making

1 and breaking electrical contact with conductors 222, 224. This  
2 causes pulsing of controlled duration and energy per unit length  
3 of the blood vessel. Those skilled in the art will appreciate  
4 that the roller 220, having a discontinuous surface, may be  
5 advantageously arranged so that it does not directly contact the  
6 EM device but rather is axially linked to a smooth roller which  
7 contacts the EM device and which is rotated by displacement of the  
8 EM device.

9

10 Referring now to Figure 5, a fourth embodiment of an  
11 automatic switch is shown. In this embodiment a roller 320 is  
12 provided with a plurality of spaced apart magnets 320a-320f and a  
13 magnetically operated switch 322 is located adjacent the roller  
14 320. The switch is coupled to the power supply of the EM device.  
15 This causes pulsing of controlled duration and energy per unit  
16 length of the blood vessel. Although the roller shown in Figure 5  
17 has a discontinuous surface like the roller shown in Figure 4, it  
18 will be appreciated that it could be formed with a smooth surface.  
19 If it is formed with a discontinuous surface, it may be  
20 advantageous to axially couple it to a roller with a smooth  
21 surface which contacts the EM device as described above.

22

23 Figure 6 illustrates a fifth embodiment of a switch which,  
24 unlike the previous embodiments, does not rely on a roller. The

1 switch 416 shown in Figure 6 has guides 418, 419, 420, 421 for  
2 guiding the EM device 412 through the switch. These guides need  
3 not be rollers nor do they need to be round or four in number. It  
4 is sufficient that they guide the EM device 412 through the  
5 switch. According to this embodiment, the switch is provided with  
6 a light source 426 (preferably a laser light source) and a light  
7 detector 428. The light detector is electrically coupled to a  
8 switching relay 430 which is coupled to the power supply of the EM  
9 device. The light source is arranged to direct a beam of light  
10 onto the surface of the EM device and the light detector is  
11 arranged to detect light reflected off surface of the EM device.  
12 The EM device 412 is provided with spaced apart stripes 413 which  
13 define areas of light reflectivity and light absorption. Those  
14 skilled in the art will appreciate that as the EM device 412 is  
15 moved through the switch 416, light from the light source 426 will  
16 be alternately reflected and absorbed by the striped surface of  
17 the EM device 412 thereby causing pulsing of the EM device. The  
18 width and spacing of the stripes determine the number of pulses  
19 per unit length of the EM device.

20

21 Figure 7 illustrates a sixth embodiment of an automatic  
22 switching arrangement. This embodiment has a pair of electrical  
23 contacts 522, 524 arranged adjacent to a movable conductor 528  
24 which is pivotally mounted at 530 and biased away from the

1 contacts by a spring 532. A V-shaped free end 526 extends from  
2 the conductor 528. This switch embodiment is intended to be used  
3 with a EM device 512 having ridges 513 on its surface. It will  
4 therefore be appreciated that when the EM device 512 is moved in  
5 the direction shown by the arrow H, the conductor 528 will move up  
6 and down in the directions indicated by arrows I making and  
7 breaking contact with the electrical contacts 522, 524. This  
8 causes pulsing of controlled duration and energy per unit length  
9 of the blood vessel.

10

11 Figures 8-10 show an embodiment of an actuator handle 600 for  
12 use with an EM device 612. The actuator preferably has a pistol  
13 shaped body 603 with a switch 616 coupled to a trigger assembly  
14 650. More particularly, the switch 616 has two rollers 618, 620  
15 which are mounted in the handle 600 and adapted to engage the EM  
16 device 612 as described above with reference to the different  
17 embodiments of a switch according to the invention. The bottom  
18 roller 620 is axially coupled to a ratchet wheel 621 as shown in  
19 Figure 9. The trigger assembly includes a ratchet wheel segment  
20 654 and a trigger 656 which are pivotally coupled to the handle at  
21 652. Figure 10 shows additional details of the trigger and  
22 ratchet assembly which could not be clearly shown in Figure 8. In  
23 particular, it can be seen that the ratchet wheel 621 has a  
24 plurality of ratchet teeth, e.g. 621a, 621,b, 621c, ...etc. The

1 ratchet wheel segment 654 is also provided with a plurality of  
2 ratchet teeth, e.g. 654a, 654b, 654c, ...etc. The trigger  
3 assembly is spring biased by a spring 632 which urges engagement  
4 of the ratchet teeth of the wheel segment 654 with the ratchet  
5 teeth of the wheel 621 as shown in Figure 10.

6

7 From the foregoing it will be appreciated that movement of  
8 the trigger 656 in the direction of the arrow J in Figure 8 will  
9 cause rotation of the rollers 620 and 621 in the direction of the  
10 arrow K which will result in the movement of the EM device 612 in  
11 the direction of the arrow L and will actuate the switch 616 as  
12 described above resulting in repeatedly pulsing the EM device.  
13 Those skilled in the art will appreciate that after the trigger is  
14 moved as far as possible in the direction of the arrow J in Figure  
15 8, it may be returned to the position shown in Figures 8 and 10  
16 either manually or by another spring (not shown) and the spring  
17 632 will allow the ratchet teeth of the wheel segment 654 to pass  
18 over the ratchet teeth of the wheel 621 without causing the wheel  
19 to move.

20

21 Figure 11 shows a seventh embodiment of the invention.  
22 According to this embodiment, the EM device 712 includes a  
23 treating channel 713 (which may be a conductor or a fiber optic  
24 depending on the type of device), an optical emission channel 715,

1 and an optical detection channel 717. The optical emission  
2 channel 715 emits a light beam toward the inner wall of the blood  
3 vessel 2 and the detection channel 717 detects the light reflected  
4 off the wall of the blood vessel 2. The emission and detection  
5 channels are coupled to optoelectric switching circuits 716 which  
6 are coupled to the power supply 714. The optical channels 715,  
7 717 and circuits 716 are configured similar to an "optical mouse"  
8 such as disclosed in U.S. Patent Number 6,501,460 which is  
9 incorporated herein by reference. As the device 712 is moved  
10 through the blood vessel 2, the optical channels 715, 717 and  
11 circuits 716 detect the amount of movement and cause the power  
12 supply to pulse the output of the treating channel according to a  
13 selected number of pulses per unit length of the blood vessel. It  
14 will be appreciated that if the treating channel output is laser  
15 light, the wavelength of the emission channel 715 is selected to  
16 be distinguishable from the laser light by the detection channel  
17 717.

18

19 There have been described and illustrated herein several  
20 embodiments of methods and apparatus for treating the wall of a  
21 blood vessel using electromagnetic energy (e.g. RF, laser, etc.).  
22 While particular embodiments of the invention have been described,  
23 it is not intended that the invention be limited thereto, as it is  
24 intended that the invention be as broad in scope as the art will

1 allow and that the specification be read likewise. Thus, while  
2 particular embodiments of switching apparatus have been disclosed,  
3 it will be appreciated that other embodiments could be realized  
4 from the teachings of the invention. In other words, it is  
5 possible to provide other apparatus which share the common feature  
6 of all of the apparatus disclosed, i.e. that the apparatus cause  
7 an automatic switching of the EM device as it is moved through a  
8 blood vessel so as to provide a set number of pulses per unit  
9 length of the blood vessel. Also, while a trigger operated hand  
10 held actuator with an automatic switch has been shown, it will be  
11 recognized that other types of actuators could be made with  
12 automatic switches according to the invention. Further, while the  
13 displacement detection means disclosed herein includes rollers,  
14 stripes on the EM device co-acting with light detection, and bumps  
15 on the surface of the EM device co-acting with a lever, those  
16 skilled in the art will appreciate that there are other ways to  
17 detect movement of the EM device. It will therefore be  
18 appreciated by those skilled in the art that yet other  
19 modifications could be made to the provided invention without  
20 deviating from its spirit and scope as so claimed.